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ID

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/324,465	06/02/99	GLUCKSMANN M	5800-2A

000826
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EXAMINER	
WANG, A	
ART UNIT	**PAPER NUMBER**
1635	9

DATE MAILED: 08/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

FILE COPY

Office Action Summary	Application No. 09/324,465	Applicant(s) Glucksman et al.
	Examiner Andrew Wang	Group Art Unit 1635

☒ Responsive to communication(s) filed on *Jul 7, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-37* is/are pending in the application.

Of the above, claim(s) *1, 3-8, 15-17, 21, 31, and 32* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *2, 9-14, 18-20, 22-30, and 33-37* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4, 7*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicants sequence listing has been received and entered into the instant specification.

2. Applicant's election of Group II, claims 2, 9-14, 18-20, and newly submitted claims 22-30 and 33-37 in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1, 3-8, 15-17, 21, 31, and 32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 8.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 2, 9-14, 18-20, 22-30, and 33-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 73, 74, 81, and 88-96 of copending Application No. 09/464,685. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pendind claims in both applications are drawn to assay methods using an antibody specific for SEQ ID NO: 1 as well as agents, including antibodies which modulate activity of SEQ ID NO: 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 2, 9-14, 18-20, 22-30, and 33-37 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The claimed invention is drawn to an antibody specific for SEQ ID NO: 1, a method of screening agents which modulate the activity or expression of SEQ ID NO: 1 and variants and fragments of SEQ ID NO: 1, and methods of treatment using said agents or antibodies.

The specification discloses the cloning and sequencing of an open reading frame, namely SEQ ID NO: 2, which when translated, displayed some homology with a G-protein coupled receptor (GPCR), based on the presence of seven transmembrane domains and a DRY triplet,

which is allegedly a GPCR motif. Moreover, the specification discloses that the cloned GPCR shares a high score with the seven transmembrane domain rhodopsin family. The specification, as filed, does not provide any evidence or guidance suggesting the claimed protein's activity or that mis-expression of the claimed proteins are involved in any particular activity or disease state. Although the specification prophetically asserts using the claimed nucleotide sequences and its encoded proteins in various protocols such and recombinant technology, hybridization, antisense inhibition, chromosomal mapping, pharmaceutical compositions to treat diseases, etc..., no evidence or guidance is provided that would suggest to a skilled artisan that there is any utility in using any of the nucleotide sequences or its encoded proteins in the asserted protocols since applicants have not adequately described any specific activity for the alleged GPCR, thereby, casting doubt on whether the nucleotide sequence or its encoded protein can be used in any of applicants asserted utilities.

Additionally, the specification's lack of a specific and substantial asserted utility or a well established utility if further supported by applicants specification which notes that GPCRs are classified into five families with distinct activities, namely, I) beta2 adrenergic receptors, II) parathyroid hormone/calcitonin/secretin receptors, III) metabotropic glutamate receptors, IV) CAMP receptors, and V) fungal mating pheromone receptors, all of which have divergent activities. Moreover, the specification notes that proteins with putative seven transmembrane domains, much like applicants, are not necessarily GPCRs such as *boss* and *fz* cloned from Drosophila. Further compounding the accurate activity prediction of the claimed protein is that a

protein's activity cannot be predicted based on primary structure alone, which is evidenced by Berendsen who teaches that "folding to the stable native state has not yet occurred, and the simulations do not contain any relevant statistics on the process" (page 643, second column). Further supporting Berendsen's teaching of unpredictability of activity prediction based on homology, Galperin *et al.* teach that "sequence comparison methods, even the best ones, are of little help when a protein has no homologs in current databases or when all database hits are to uncharacterized gene products". Furthermore, Galperin *et al.* disclose "assessing the actual power of the context-based method for protein function prediction requires extensive testing by labor-consuming, case-by-case computational, and eventually experimental analysis".

Therefore, as discussed above, neither the art nor the specification as filed provides a specific and substantial asserted utility or a well established utility for the claimed nucleotide or amino acid sequences thereby casting doubt on the utility of the claimed antibodies and methods for agent screening and treatment as well as their asserted utilities. Lastly, since there was no specific and substantial asserted utility or a well established utility for the disclosed nucleic acids and encoded proteins, credibility of the utility was not assessed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2, 9-14, 18-20, 22-30, and 33-37 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

6. Claims 2, 9-14, and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 9-14, and 18-20 are indefinite since they depend upon a non-elected claim 1.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Wang whose telephone number is (703) 306-3217. The examiner can normally be reached on Monday to Thursday from 7:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Andrew Wang
August 24, 2000

Andrew Wang
Patent Examiner
Technology Center 1600